

Remarks

A. Support for Amendments

Support for identifying the gel as "a silicone" gel may be found at page 2, line 5, page 6, line 20, and page 7, lines 3-7.

Support for identifying the loop portion as "a stretchable loop" may be found at page 3, lines 9-11 where "rigid yet stretchable loop portions that have a modulus of elasticity of about 50%, with no stretch memory" are described.

Support for identifying the material as "a composite" may be found on page 1 at lines 15 to 18 where a "composite material consisting of two layers" is described.

B. § 102(b) Rejection Over U.S. 4,991,574

Claims 1-2 and 28-29 are rejected under 35 U.S.C. 102(b) as anticipated by U.S. 4,991,574 (Pocknell). With respect to Claim 1, the Examiner states that Pocknell discloses at col. 1, lines 57-61 and in Fig. 1 a stretchable, supportive bandage comprising a gel layer 2 bonded to a stretchable carrier 3. The Examiner considers the bonded surfaces of the gel layer 2 and carrier layer 3 to be the respective adhesion surfaces of each material. The Examiner points out that the method of forming the product is not relevant to the issue of the product's patentability and hence the "bonding" limitation in the claims has not been given patentable weight. With respect to Claim 2, the Examiner states that Pocknell discloses at col. 1, lines 57 and 61 and Figure 1 that the gel layer 2 comprises silicone. With respect to Claim 28, the Examiner states that Pocknell discloses at col. 2, lines 57-61 that the gel layer 2 may contain additives. With respect to Claim 29, the Examiner notes that the method of forming the product is not relevant to the issue of the patentability of the product itself. Applicants state that the formation of a sheet or roll is for manufacturing purposes and that the final shape can be of limitless configurations (citing page 5, lines 8-13). Therefore, this limitation has not been given patentable weight.

C. Applicants' Response to §102(b) Rejection Over U.S. 4,991,574

It is respectfully pointed out that Pocknell's carrier is not "an elastic and supportive" carrier - it is not "a stretchable" carrier. Pocknell's carrier is a thin film of a silicone elastomer which has a thickness from about 0.01 cm to about 0.1 cm. Pocknell teaches that thicker films can be used but the thicker films "... reduce the ability of the gel sheet to conform to the body contour and offer no compensating advantages" (see column 2, lines 36-40). In contrast, Applicants' carrier is elastic and supportive. It is the rigid yet stretchable loop portion of a hook and loop fastener. It has a high modulus of elasticity and no

stretch memory. Thus, Claims 1-2 and 28-29 cannot be anticipated by Pocknell who tracks a non-supportive and non-elastic carrier.

D. §102(b) Rejection Over 5,891,076

Claims 1-2 and 28-29 are rejected under 35 U.S.C. 102(b) as anticipated by U.S. 5,891,076 (Fabo '076).

With respect to Claim 1, the Examiner states that Fabo '076 discloses at Fig. 1 and at col. 3, line 62, and col. 4, line 13 a supportive, stretchable bandage comprising a gel layer 2, 3 and a stretchable carrier. The Examiner again, points out that the method of forming the product is not relevant to the issue of the product's patentability. Therefore, the limitation of "bonding" the adhesion surface has not been given patentable weight. With respect to Claim 2, the Examiner states that Fabo '076 discloses that the gel layer comprises silicone. With respect to Claim 29, the Examiner notes that Applicants have stated that the formation of a sheet or roll is for manufacturing purposes and that the final shape of the claimed invention can be of limitless configurations (citing page 5, lines 8-13). The Examiner again points out the method of forming the product is not relevant to the product's patentability and therefore this limitation has not been given patentable weight.

E. Applicants' Response To §102(b) Rejection Over U.S. 5,891,076

It is respectfully submitted that applicants' stretchable, supportive bandage is not anticipated by the '076 patent's hypertrophic scar dressing which includes continuous layers of silicone gel on both sides of the carrier material. Fig. 1 shows the gel layers 2 and 3 surrounding the flexible carrier sheet 1. Applicants' two-ply composite has a silicone gel layer on one side and an elastic and supportive carrier layer on the other side.

F. §102(b) Rejection Over U.S. 5,340,363

Claims 1-2 and 28-29 are rejected under 35 U.S.C. 102(b) as anticipated by U.S. 5,340,363 (Fabo '363).

With respect to Claim 1, Fabo the Examiner states that '363 discloses at col. 2, lines 4-16 a supportive, stretchable bandage comprising a gel layer 2 and a stretchable carrier layer 1. The Examiner again notes that the process for forming the product by bonding adhesion layers has not been give patentable weight. With respect to Claim 2, the Examiner states that Fabo '363 discloses at col. 2, lines 27-35 that the gel layer 2 comprises silicone. With respect to Claim 28, the Examiner states that Fabo

'363 discloses at col. 3, lines 30-36 that the gel layer 2 may contain additives. With respect to Claim 29, the Examiner again has not given patentable weight to the formation of the bandage into a sheet or roll.

G. Applicants' Response To §102(b) Rejection Over U.S. 5,340,363

It is respectfully submitted that Fabo '363 does not disclose a supportive, stretchable bandage comprising "an elastic and supportive carrier" which is "stretchable". Rather, Fabo '363 discloses a wound dressing having a thickness of about 0.2-1.5 mm (see Claim 1). The dressing includes a carrier material such as a non-woven material, a knitted or woven textile material, or a perforated plastic film (see Claim 7). The carrier material is enclosed in a silicone gel "so that said gel forms continuous layers on both sides of the carrier material and essentially covers the whole of said both sides" (see Claim 1, emphasis added). In Applicant's claimed two ply composite the silicone gel is only on one side, i.e., the skin side of the composite, not on both sides.

H. §103 Rejection Over U.S. 4,991,574 or U.S. 5,891,076 or U.S. 5,340,363

Claim 3 is rejected under 35 U.S.C. 103(a) as obvious over Pocknell '574, Fabo '076, or Fabo '363.

According to the Examiner, Pocknell and Fabo both disclose the claimed invention except for the carrier having an elastic modulus of about 50%. The Examiner believes that, although neither Pocknell nor Fabo discloses an elastic modulus of about 50% both do teach "stretchable" bandages and hence therefore, it would have been obvious to one of ordinary skill in the art to provide for a carrier with an elastic modulus of about 50%. The Examiner notes that since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

I. Applicants' Response To §103(a) Rejection Over U.S. 4,991,574 or U.S. 5,891,076 or U.S. 5,340,363

The claimed stretchable supportive bandage where the carrier has an elastic modulus of about 50% cannot be obvious over Pocknell's thin film (0.01 – 0.1 cm.) of a silicone elastomer, over Fabo '076's flexible carrier sheet (0.03 – 1 mm.), or over Fabo '363's textiles (woven or non-woven) or perforated plastic film. Such materials are not supportive as is the claimed carrier which is the stretchable loop portion of a hook and loop fastener. The Pocknell and Fabo materials are not stretchable and could not have the claimed modulus.

J. §103(a) Rejection Over U.S. 5,891,076 In View of U.S. 5,340,363

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fabo '076 in view of Fabo '363. According to the Examiner, Fabo '076 discloses the claimed invention except for the gel layer containing additives. Fabo '363 teaches a bandage having a carrier layer 1 and a gel layer 2 that may contain additives to relieve pain or stimulate wound repair. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify Fabo '076 by incorporating additives into the gel layer as taught by Fabo '363 since doing so would provide additional avenues for pain relief and wound repair stimulation for the patient.

K. Applicants' Response To §103(a) Rejection Over U.S. 5,891,076 In View of U.S. 5,340,363

The teachings of Fabo '363 do not cure the deficiencies of Fabo '076 which teaches a hypertropic flexible wound dressing with silicone gel on both sides of a liquid permeable material such as a soft, flexible, and elastically extendable netting. Applicants' stretchable supportive bandage is "a continuous two ply composite" where one surface is a silicone gel layer and the other surface is an elastic, supportive, stretchable carrier.

L. Provisional Obviousness - Type Double Patenting Rejection Over Ser. No. 09/931,974

Claims 1-5, 29-31, and 33-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over Claims 4 and 5 of copending Application No. 09/931,974. Although the conflicting claims are not identical, the Examiner believes they are not patentably distinct from each other because Claims 4-5 of the earlier copending application "anticipate" Claims 1-2, 4-5, 30 and 35-36 of the current application.

With respect to present Claims 1-2, 4, and 30, Claim 4 of the '974 application discloses a bandage to be fastened about a body part comprising a silicone gel layer and an elastic carrier layer made of the loop portion of a hook and loop fastener while present Claim 1 covers a bandage comprising a gel layer and a stretchable carrier and further comprising a silicone gel (Claim 2) and a loop fastener (Claim 4), which are collectively disclosed again in present Claim 30.

With respect to present Claims 5 and 35-36, Claim 5 of the 1974 application covers the bandage of Claim 4 further comprising a closure strip having a hook fastener for securing the bandage about a

body part, whereas present Claim 5 covers the same closure strip. These items are separately claimed again in present Claims 35 and 36.

Present Claims 3 and 33 disclose a bandage having a modulus of about 50%. The Examiner believes that it would have been obvious to one of ordinary skill in the art to provide for a carrier with an elastic modulus of about 50% since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Present Claims 29 and 34 set forth a bandage that is in the form of a sheet or a roll. However, the applicant states that the formation of a sheet or roll is for manufacturing purposes and that the final shape of the claimed invention can be of limitless configurations (citing page 5, lines 8-13). The Examiner states that the method of forming the product is not relevant to the issue of product's patentability. Therefore, this limitation has not been given patentable weight.

Present Claim 31 covers a silicone gel which is a cured polydiorganosiloxane resin. The Examiner believes it would have been obvious to one of ordinary skill in the art to create a silicone gel from a cured polydiorganosiloxane resin since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Present Claim 37 sets forth that the bandage is wrapped around a joint or muscle and Claim 38 further limits the joint to a knee, ankle, wrist, or an elbow. It has been held that a recitation with respect to the manner in which a claimed invention is intended to be used does not differentiate the claimed invention from prior art satisfying the claimed structural limitations.

Present Claim 39 covers the use of the bandage for veterinary applications. It has been held that a recitation with respect to the manner in which a claimed invention is intended to be used does not differentiate the claimed invention from prior art satisfying the claimed structural limitations.

Thus, the Examiner believes that the Claims 4-5 of the earlier application encompass Claims 1-5, 29-31, and 33-39 of the present application. Following the rationale in In re Goodman, where the applicant has once been granted a patent containing a claim for the specific or narrower invention, the applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

M. Applicants' Response To Provisional Double Patenting Rejection Over Ser. No. 09/931,974

If granted, Applicants will file a Terminal Disclaimer to overcome this provisional rejection.

N. Provisional Obviousness - Type Double Patenting Rejection over Ser. No. 09/931,974 in view of U.S. 5,340,363

Claims 28 and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over the above references. As discussed above, Fabo '363 teaches a bandage having a carrier layer 1 and a gel layer 2 which may contain additives that relieve pain or stimulate wound repair. Hence, the Examiner believes it would have been obvious to one of ordinary skill in the art to modify Claim 4 of the pending application by incorporating an additive into the gel layer as taught by Fabo '363 since doing so would provide additional avenues for pain relief and repair stimulation for the patient.

O. Applicants' Response to Provisional Double Patenting Over Ser. No. 09/931,974 in view of U.S. 5,340,363

It is respectfully submitted that the teaching of Fabo '363, i.e., adding pain - relieving substances or antibacterial agents to "a liquid permeable, porous mesh sheets of a wound dressing encapsulated with a cross-linked tacky silicone gel" can not render obvious adding an additive to the gel layer of a stretchable, supportive bandage which is a two ply composite of a silicone gel and an elastic and supportive carrier which is the stretchable loop portion of a hook and loop fastener.

P. Drawings

In Serial No. 09/931,974 (the parent application), the drawings were objected because the Examiner believed reference characters "5" and "40" were both used to designate the same gel layer. Reference "40", however, is the uncured gel compound which has been applied to the stretchable carrier 10 by passing the carrier onto a bath of uncured gel material as shown in Figure 5 or by depositing the uncured gel material onto the stretchable carrier as shown in Figure 6. In contrast, reference "5" in Figure 2 is the cured gel layer. Note the heating element in both Figures 5 and 6 where the gel is cured. See also the text at page 12, lines 7-8 as well as lines 16

to 18 regarding combining the gel and carrier and then curing the combined carrier and gel in a heating oven.

The reference to "heating element" in Figures 6 and 7 will be changed to reference character "50" and the specification has been amended to include this reference number.

If requested, corrected drawings will be provided where Figure 5 precedes Figure 6.

Q. Closing

Entry of this amendment and an early allowance is respectfully requested. No new matter is presented.

Respectfully submitted,

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